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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/371,333 08/10/99 XU

W 98-10D1

HM22/1106

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EXAMINER

ULM, J

| ART UNIT | PAPER NUMBER |
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1646

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DATE MAILED: 11/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                              |                                      |                                  |
|------------------------------|--------------------------------------|----------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>09/371,333</b> | Applicant(s)<br><b>Xu et al.</b> |
|                              | Examiner<br><b>John Ulm</b>          | Group Art Unit<br><b>1646</b>    |

Responsive to communication(s) filed on Aug 10, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 12-39 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) 25 and 28-38 is/are allowed.

Claim(s) 12, 24, 26, 27, and 39 is/are rejected.

Claim(s) 13-23 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1) Claims 12 to 39 are pending in the instant application. Claims 1 to 11 have been canceled and claims 12 to 39 have been added as requested by Applicant in Paper Number 2, filed 10 August of 1999.

2) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For example, page 6 of the instant specification contain numerous references to nucleotide sequences without employing the required sequence identifiers. Correction is required. See M.P.E.P. 2422.03.

3) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the nucleotide sequences on page 6 and the amino acid sequences presented on page 12 of the instant specification. Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. §

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1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

4) Claims 25 and 28 to 38 are allowable as written.

5) Claims 13 to 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

35 U.S.C. 101 reads as follows:

10 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15 6) Claim 27 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility. As indicated by the text in the last paragraph on page 63 of the instant application the invention, as claimed, is inoperable and, therefore, not useful. Whereas the instant specification does not identify a specific utility for the nucleic acid described therein, an artisan would readily recognize that a nucleic acid encoding a functional human thrombin receptor is useful in identifying agonists and antagonists thereto.

20 However, the specific embodiment of thrombin receptor encoded by the nucleic acid of claim 27 is expressly disclosed in the instant specification as inoperative, and an artisan would not find a nucleic acid encoding an inoperable thrombin receptor to be particularly useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7) Claim 27 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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8) Claims 12 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain an adequate written description of an isolated nucleic acid encoding a protease activated receptor or portion thereof having other than all or a specific portion of the amino acid sequence presented in SEQ ID NO.2 of the instant application. In the decision of *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997), the court held that:

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"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by

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describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

5 An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 10 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The instant specification does not provide a detailed written description of an isolated nucleic acid encoding "an allelic variant" or "splice variant" of the single protein described therein.

15 9) Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim encompasses an isolated nucleic acid encoding a polypeptide having an amino acid sequence which can deviate from residues 18 to 78 of SEQ ID NO:2 by as many as 6 20 amino acid residues. The only disclosed specific and substantial use for such a nucleic acid is in the production of the polypeptide encoded thereby. The only specific and substantial utility for a polypeptide encoded by the claimed nucleic acid is as an agonist for the thrombin receptor identified in the instant specification as PAR4. The instant claims encompass nucleic acids which

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can encode thousands of different embodiments of the disclosed polypeptide. The instant specification, however, only describes two embodiments of the disclosed polypeptide. One is a naturally occurring peptide found as a tethered ligand of the receptor protein described in the instant specification and the second polypeptide contains a single amino acid substitution and is inoperable. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not identify those amino acid residues in residues 18 to 78 of SEQ ID NO:2 which are critical to the functionality of a PAR4 ligand and those residues which are expendable or substitutable, identify an analogous protein for which this information is known or provide even a single example of a nucleic acid encoding a functional polypeptide whose amino acid sequence has been intentionally altered at even a single residue, an artisan can not make a nucleic acid encoding a polypeptide of the instant invention which deviates from the single naturally occurring polypeptide in any way and predict "by resort to known scientific law" if the encoded polypeptide will function as a PAR4 ligand.

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10) Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method recited in claim 39 requires a polynucleotide probe which hybridizes to a reference nucleic acid. It is well known in the art that any polynucleotide will "hybridize" to any other polynucleotide, irrespective of sequence similarity, under appropriate conditions. This is why denaturing agents such as increased temperature and formamide are employed to inhibit non-specific hybridization. To simply employ any polynucleotide probe which meets the current hybridization limitations of this claim in the method recited therein will not result in the detection 10 of nucleic acids encoding a PAR4 protein of the instant invention. A critical element of the disclosed method is the conditions under which the probe is required to hybridize to the referenced nucleic acid, and these conditions are not recited in the claim.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

20 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800